The Prescription Drug Affordability Act of 2015

Americans pay – by far – the highest prices in the world for prescription drugs. For example, in 2013, the U.S. spent nearly 40 percent more on prescriptions per person than Canada, the next-highest OECD spender, twice as much as the average major industrialized country, and nearly five times as much as Denmark. A 2014 survey by the Commonwealth Fund found nearly twenty percent of the population between the ages of 19 and 64, or 35 million people, did not fill a prescription because they could not afford it, which can lead to worse health outcomes. The Prescription Drug Affordability Act would lower these high prices and increase access to medications through the following policies:

MEDICARE PART D NEGOTIATION

This legislation would instruct the Secretary of HHS to negotiate drug prices under the Medicare Part D prescription drug program. According to a 2013 report by the Center for Economic and Policy Research (CEPR), the federal government could save as much as \$541 billion over ten years by negotiating for prices similar to those paid in other major industrialized countries.

PRESCRIPTION DRUG REIMPORTATION FROM CANADA

The bill would allow individuals, pharmacists, and wholesalers to import prescription drugs from licensed Canadian pharmacies. The bill instructs the Secretary to issue regulations already required under current law by January 1, 2016, and would also delay regulations on the destruction of imported drugs until the rule for legally importing drugs is finalized.

The bill also directs the United States Trade Representative to reject provisions in the negotiation of any trade agreement that would raise drug prices in the U.S., extend periods of patent exclusivity, or remove flexibilities in U.S. law regarding drug pricing.

MEDICARE AND MEDICAID REBATES

The bill would restore the minimum rebate on drugs covered under Medicare Part D for low-income Medicare beneficiaries, which was eliminated with the creation of Part D. According to CBO, rebates would save \$103 billion over 10 years.

The legislation would also require generic drug manufacturers to pay an additional rebate to Medicaid if their drug prices rise faster than inflation, mirroring the current requirements for brand name drug makers. According to CBO, these rebates would save \$1 billion over 10 years.

The bill would also close the Medicare Part D donut hole for brand and generic drugs by 2017, three years earlier than under current law.

PROHIBIT PAY-FOR-DELAY DEALS

The bill would prohibit anti-competitive arrangements between brand and generic drug makers where the brand name drug manufacturers pays the generic manufacturer to delay bringing their generic alternative to market. According to the FTC, these anticompetitive deals cost consumers and taxpayers at least \$3.5 billion in higher drug costs every year. In FY 2012, the FTC found

that there were 40 potential pay-for-delay deals involving 31 branded products with combined U.S. sales of \$8.3 billion.

PENALTIES FOR FRAUD CONVICTIONS

The legislation would terminate any remaining market exclusivity period on any product found in violation of criminal or civil law through a federal fraud conviction or settlement. Over the last decade, most major branded drug makers have either settled or been convicted of fraud for violations including off-label promotion, kickbacks, anti-monopoly practices, and Medicare fraud.

DRUG PRICING AND COST TRANSPARENCY

The bill would require pharmaceutical companies to publicly report information that affects drug pricing, including the total costs incurred for research and development and clinical trials, as well as the portion of drug development expenses offset by tax credits or paid by federal grants.

The legislation also requires drug companies to report not only the price information charged to federal payers, but also requires companies to submit prices, profits, and sale information in other countries in which those products are sold.